K093234

GE Healthcare
510(k) Premarket Notification Submission

510(k) Summary

OCT 30 2009

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	October 8th, 2009
Submitter:	GE Healthcare, (GE Medical Systems SCS) 283, rue de la Minière 78530 Buc - FRANCE
Primary Contact Person:	Sophie Le Loarer Regulatory Affairs Specialist GE Healthcare, (GE Medical Systems SCS) TEL: (33) 1 30 70 43 31 - FRANCE FAX: (33) 1 30 70 41 00 - FRANCE
Secondary Contact Person:	Stephen G. Slavens, RAC Global Regulatory Affairs Director GE Healthcare, (GE Medical Systems LLC) TEL: (262) 548-4992 FAX: (262) 548-3884
Device: Trade Name:	INTEGRATED REGISTRATION
Common/Usual Name:	INTEGRATED REGISTRATION
Classification Name: Product Code:	21CFR 892.2050 Picture archiving and communications system 90LLZ
Predicate Devices:	K010336: Advantage Windows CT/PET Fusion K983256: Advantage Windows (CT/MR) Fusion K022310: Advantage Windows X-Ray/MR Fusion
Device Description:	The INTEGRATED REGISTRATION tool runs on Advantage Workstation 4.5 or higher versions. This product is an extension to the Volume Viewer application, dedicated to the registration of multi-modality images, and comparison of volumetric datasets from Computed Tomography (CT), Magnetic Resonance (MR), Positron Emission Tomography (PET) or Single Photon Emission Computed Tomography (SPECT), and 3D X-Ray Angiography (XA). Note that the INTEGRATED REGISTRATION licenses control which algorithms are available and which modalities can be saved.
Intended Use:	INTEGRATED REGISTRATION permits comparison of three-dimensional (3D) images from Computed Tomography (CT), Magnetic Resonance Imaging (MRI), Emission Tomography (PET or SPECT) and X-Ray Angiography (XA) to help physicians in diagnostic radiology or therapy planning.

Technology:	INTEGRATED REGISTRATION consists of optimized registration algorithms for pairs of modality images, configuration options as licensed by the end user, and protocols for use within each configuration option. INTEGRATED REGISTRATION is an optimized combination of its predicate devices and employs the same fundamental scientific technology as these predicate devices. Major improvements to the device include: • 2D, 3D and hybrid 2D/3D Fusion capabilities • The ability to load multiple (more than two) series and multiple modalities (CT, MR, PET, SPECT, XA) in the same registration session • Registration results propagation to all the supported modalities • Optimized algorithms for modality pairs and anatomies • Default registration at load • Optimized tools for manual and regional registration, • Reset, center and undo/redo tools to improve the usability, • Protocols and layouts dedicated to typical clinical use cases, • Saving ability for the new DICOM Registration Object • Easier access to GE Radiotherapy simulation software: Advantage Sim MD
Determination of Substantial Equivalence:	Summary of Non-Clinical Tests: INTEGRATED REGISTRATION complies with DICOM Standard NEMA PS 3.1 - 3.18(2008). The following quality assurance measures were applied to the development of the system: • Risk Analysis • Requirements Reviews • Design Reviews • Performance testing (Verification) • Safety testing (Verification) • Final acceptance testing (Validation) Summary of Clinical Tests: The subject of this premarket submission, INTEGRATED REGISTRATION, did not require clinical studies to support substantial equivalence.
Conclusion:	GE Healthcare considers the INTEGRATED REGISTRATION Software application to be as safe, as effective, and performance is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

General Electric Medical Systems SCS
% Mr. Daniel W. Lehtonen
Senior Staff Engineer-Medical Devices
Intertek Testing Services NA, Inc.
2307 East Aurora Road, Unit B7
TWINSBURG OH 44087

OCT 30 2009

Re: K093234
Trade/Device Name: Integrated Registration
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 14, 2009
Received: October 15, 2009

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K093234

Device Name: INTEGRATED REGISTRATION

Indications for Use:

INTEGRATED REGISTRATION provides easy means for comparison of three-dimensional (3D) images from Computed Tomography (CT), Magnetic Resonance Imaging (MRI), Emission Tomography (PET or SPECT) and X-Ray Angiography (XA). To help physicians in diagnostic radiology or therapy planning, INTEGRATED REGISTRATION allows 3D registration between volumetric acquisitions that may come from the same acquisition modality or from different acquisition modalities.

Prescription Use_X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K093234